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Federal Office of Consumer Protection and Food Safety  
Mauerstraße 39-42  
10117 Berlin  
(Germany)**

**DECENTRALISED PROCEDURE**

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY  
MEDICINAL PRODUCT**

**Animeloxan, 5 mg/ml**

**Date: 21. August 2018**

## MODULE 1

### PRODUCT SUMMARY

EU Procedure number	DE/V/0311/001/DC
Name, strength and pharmaceutical form	Animeloxan, 5 mg/ml, Solution for Injection for Dogs and Cats
Applicant	aniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell GERMANY
Active substance(s)	Meloxicam
ATC Vetcode	QM01AC06
Target species	Dogs, Cats
Indication for use	Dogs: Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery. Cats: Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

## **MODULE 2**

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicinal Agencies website ([www.hma.eu](http://www.hma.eu)).

## **MODULE 3**

### **PUBLIC ASSESSMENT REPORT**

Legal basis of original application	Application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original Decentralised procedure	26 <sup>th</sup> October 2011
Date product first authorised in the Reference Member State (MRP only)	Not applicable.
Concerned Member States for original procedure	AT, PL and UK (former RMS)

#### **I. SCIENTIFIC OVERVIEW**

This was a decentralised application for a generic product, submitted in accordance with article 13 (1) of Directive 2001/82/EC, as amended. The indication in dogs is for the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders and the reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery. In cats, the indication is for Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released on the market. It has been shown that the product can be safely used in the target species, the slight reactions observed are indicated in the SPC.<sup>1</sup>

The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

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<sup>1</sup> SPC – Summary of product Characteristics,

## II. QUALITY ASPECTS

### **A. Composition**

The product contains 5 mg/ml meloxicam and excipients N-Methyl 2- pyrrolidone, ethanol, anhydrous, sodium hydroxide, hydrochloric acid, dilute and water for injection.

The container/closure system consists of clear glass (Type I) bottles of 10 ml 20 ml and 25 ml, closed with bromobutyl rubber stoppers and fixed with Aluminium caps or Aluminium /PP flip caps. The product is available in boxes containing 1 x 10 ml or 5 x 10 ml and 1 x 20 ml or 5 x 20 ml, and 1 x 25 ml or 5 x 25 ml, not all pack sizes may be marketed. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the presence of preservative are justified.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

### **B. Method of Preparation of the Product**

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. Process validation data on the product have been presented in accordance with the relevant European guidelines.

### **C. Control of Starting Materials**

The active substance is meloxicam, an established active substance described in the European Pharmacopoeia (Ph. Eur). The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided. All excipients comply with appropriate Ph. Eur monographs.

### **D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies**

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

### **E. Control on intermediate products**

Not applicable.

#### **F. Control Tests on the Finished Product**

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product. Satisfactory validation data for the analytical methods have been provided. Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification. Control tests on the finished product are adequate for the pharmaceutical form.

#### **G. Stability**

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions. Long term, intermediate and accelerated studies demonstrated the appropriateness of the product to retain a three year shelf-life.

#### **H. Genetically Modified Organisms**

Not applicable.

#### **J. Other Information**

Shelf-life of the product as stored for sale: 3 years.  
Shelf-life of the product after first opening: 28 days.

### **III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)**

Warnings and precautions as listed on the product literature are adequate to ensure safety of the product to users and the environment.

#### **III.A Safety Testing**

##### **User Safety**

The applicant has provided a user safety assessment in compliance with the relevant guideline, (CVMP<sup>2</sup> EMEA/CVMP/543/03-Final), citing that only professionals (veterinarians, farmers) will use the product, and that the main route of exposure is the dermal route. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product:

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<sup>2</sup> CVMP – The Committee for Medicinal Products for Veterinary Use.

- Accidental self-injection may give rise to pain. People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
- If accidental skin contact occurs, wash the affected area thoroughly.
- Wash hands after use.
- In view of the risk of accidental self-injection and the known adverse class-effects of NSAIDs and other prostaglandin inhibitors on pregnancy and/or embryofetal development, the veterinary medicinal product should not be administered by pregnant women or women attempting to conceive.

### **Ecotoxicity**

The applicant provided a Phase I environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. The assessment concluded that environmental exposure will not be large, as the product will only be used to treat individual animals.

Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

## **IV CLINICAL ASSESSMENT (EFFICACY)**

Although this was a generic product, bioequivalence and tolerance studies were required in order to permit the use of the product via the subcutaneous route.

### **IV.A Pre-Clinical Studies**

#### **Pharmacology**

Bioequivalence studies were performed in both dogs and cats according to the guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.2; 2011).

#### Dogs

*In-vivo* bioequivalence could be demonstrated between the two products in an experimental bioequivalence study after subcutaneously administration of the intended dose in dogs (0.2 mg meloxicam/kg body weight) using the test and reference product. The confidence intervals of the ratios of AUC and C<sub>max</sub> were within the acceptance range.

## Cats

*In-vivo* bioequivalence could be demonstrated between the two products in an experimental bioequivalence study after subcutaneously administration of the intended dose in cats (0.3 mg meloxicam/kg body weight) using the test and reference product. The confidence intervals of the ratios of AUC and Cmax were within the acceptance range.

### ***Tolerance in the Target Species of Animals***

Good tolerance was established in both target species. Any adverse reactions are cited on the SPC and product literature.

## ***IV.B Clinical Studies***

### ***Laboratory Trials***

As this was a generic application submitted under Article 13 (1) of Directive 2001/82/EC as amended, and a reference product was already established, no data were required for this section.

### ***Field Trials***

As this was a generic application submitted under Article 13 (1) of Directive 2001/82/EC as amended, and a reference product was already established, no data were required for this section.

## **V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT**

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

## MODULE 4

### POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Heads of Veterinary Medicinal Agencies website ([www.hma.eu](http://www.hma.eu)).

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

•	13. March 2019	C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/ biosimilar medicinal products following assessment of the same change for the reference product a) Implementation of change(s) for which no new additional data is required to be submitted by the MAH
•	21 August 2018	RMS change from UK to DE
•	24 April 2018	Deletion of a manufacturing site for an active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	06 December 2017	Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years.
•	20 April 2017	Renewal – UK as RMS.
•	23 March 2017	Change in address of manufacturer of the finished product. Replacement of a manufacturer for secondary packaging.

•	22 June 2016	Addition of a site where batch control/testing takes place. Addition of a manufacturer responsible for batch release, not including batch control/testing. Addition of a secondary packaging site of the finished product. Replacement of a secondary packaging site of the finished product. Replacement of a manufacturing site for the manufacturing process of the finished product
•	30 March 2016	Deletion of a manufacturing site of the active substance. Submission of an updated Certificate of Suitability
•	10 July 2014	Submission of a new Ph. Eur. Certificate of Suitability for a new manufacturer of the active substance.
•	07 December 2012	To change the QPPV